K033562
1 of 2

DEC 12 2003

BARD ENDOSCOPIC TECHNOLOGIES
C.R. Bard, Inc.
129 Concord Road
P.O. Box 7031
Billerica, MA 01821-7031
978-663-8989

BARD

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

A. Submitter Information:

Submitter's Name:	C.R. Bard, Inc., Bard Endoscopic Technologies Division
Submitter's Address:	129 Concord Road, Billerica MA 01821-7031
Contact Person:	Thomas Hirte
Contact Person's Telephone Number:	(978) 262-4867
Contact Person's FAX Number:	(978) 262-4878

B. Device Name:

Fastrac™ Gastric Access Port Pull Kit
Fastrac™ Gastric Access Port Guidewire Kit
Fastrac™ Gastric Access Port Pull Safety System
Fastrac™ Gastric Access Port Guidewire Safety System

C. Predicate Devices:

Fastrac™ Gastric Access Port Pull PEG System (K972025),
Fastrac™ Gastric Access Port Guidewire PEG System (K972102)

D. Device Description:

The FASTRAC™ Gastric Access Port device is a silicone balloon-type feeding product designed for percutaneous initial endoscopic placement (via a *Pull* placement technique, or a *Guidewire* placement technique) of a long term initial feeding and/or decompression gastrostomy tube. The feeding tube is designed with soft thin silicone tubing, which is wire-reinforced to prevent kinking, and the external bolster positions the device at a 90° angle against the abdomen.

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E. Intended Use:

The Fastrac™ Gastric Access Port System is intended for percutaneous placement, and long term initial feeding and/or decompression gastrostomy.

F. Technological Characteristics Summary:

The FASTRAC™ Gastric Access Port device is a silicone balloon-type feeding product designed with soft thin silicone tubing, which is wire-reinforced to prevent kinking. The external bolster positions the device at a 90° angle against the abdomen.

G. Performance Data:

Design verification data demonstrated that the Fastrac™ Gastric Access Port System meets the same performance requirements and is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2003

Thomas Hirt, P.E.
Senior Regulatory Affairs Specialist
Bard Endoscopic Technologies
C.R. Bard, Inc.
129 Concord Road
P.O. Box 7031
BILLERICA MA 01821-7031

Re: K033562
Trade/Device Name: Fastrac™ Gastric Access Port System
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: November 10, 2003
Received: November 12, 2003

Dear Mr. Hirt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807);

labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains 1% lidocaine HCL, lubricating jelly, povidone iodine swabs, and povidone iodine ointment which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/dsma/dsmamain.html.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): TBD K033562

Device Name: Fastrac™ Gastric Access Port System

Indications For Use: The Fastrac™ Gastric Access Port System is indicated for percutaneous placement of a long term initial feeding and/or decompression gastrostomy device.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use ____ (Optional Format 1-2-96)

David A. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033562